Mr. Speaker, I ask the U.S. House of Representatives to join me in thanking Sheriff Lawrence "Lumpy" Leveille for his nearly 40 years of service to the people of St. Ignace, Mackinac County and to the State of Michigan and wish him well in his new position. Lawrence "Lumpy" Leveille's commitment to community and to justice has been a model of public service.

A TRIBUTE TO ELMER HAMILTON

HON. DAVID SCOTT

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 28, 2005

Mr. SCOTT of Georgia. Mr. Speaker, I rise today in recognition of Mr. Elmer Hamilton, a civil-rights activist, a crusader for labor rights, a loving husband, and a caring father and grandfather. On August 20, 2005, Elmer will retire from a 45-year career in community and public relations and the organized labor movement.

Mr. Hamilton's life of service began in 1953 when he enlisted in the Navy, eventually serving as a machinist mate. After his military service, Elmer's commitment to civil rights led him to work on voter registration drives in Alabama and Mississippi and organize against racial discrimination in Georgia. He also served as a special assistant to Southern Christian Leadership Conference leader Ralph David Abernathy during his congressional bid.

Elmer's served in various community relations capacities in New York and South Carolina providing educational and job placement services to community members. At one point he served as a community organizer for the Brooklyn, NY, Borough President.

After moving to Georgia, Elmer worked in public transportation as a bus operator for MARTA, the Metro Atlanta Rapid Transit Authority. He became the president of the Amalgamated Transit Union, Local 732 where he negotiated contracts for over 3,000 transit employees from MARTA, Cobb County Transit, and Gwinnett County Transit. When he retires, he will also leave his post as a board member of the AFL–CIO representing the Coalition of Black Trade Unionists.

Mr. Speaker and colleagues, please join me, Elmer's wife, Peggy, his six children and two grandchildren in congratulating Elmer on a fulfilling career. Best wishes, Elmer, and enjoy your retirement.

MEDICAL DEVICE USER FEE STABILIZATION ACT OF 2005

SPEECH OF

HON. JOE BARTON

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Tuesday, July 26, 2005

Mr. BARTON of Texas. Mr. Speaker, on October 26, 2002, the Medical Device User Fee and Modernization Act, MDUFMA, was signed into law.

I. BACKGROUND AND NEED FOR LEGISLATION

MDUFMA amended the Federal Food Drug and Cosmetic Act, FFDCA, to authorize the Food and Drug Administration, FDA, to collect user fees from manufacturers who submit certain applications to market medical devices. The premise behind initiating a user fee program for medical devices was to provide for more timely and predictable review of medical device applications, as well as to make the necessary infrastructure investments required to conduct the review of increasingly complex medical device applications in the future in a timely and predictable fashion.

The FFDCA as amended by MDUFMA, authorizes FDA to collect user fees for certain medical device applications in FY 2006 and FY 2007 only if certain conditions are met. MDUFMA specifies that for FY 2006 fees may not be assessed if the total amounts appropriated for FY 2003 through FY 2005 for FDA's device and radiological health program did not meet certain targets. Appropriations for FY 2003 through FY 2005 for FDA's device and radiological health program were below the amount specified in MDUFMA. This legislation modifies those conditions, minimum appropriation levels for FY 2003 through FY 2005, to allow FDA to continue to collect user fees until October 1, 2007.

User fees make possible investments in information technology infrastructure and human capital, more comprehensive training for reviewers, greater use of experts in academia and the private sector, enhanced project management, increased guidance development, expanded participation in globalization and standards setting activities, and increased interaction with industry both before and during the application review process. As medical device applications become progressively more complex, this investment will become ever more necessary to keep up with performance standards that FDA has thus far been successful in meeting. Keeping the device review program on sound financial footing is essential to ensure timely and predictable review of medical device applications. Providing the device review program with sufficient resources to fulfill its mission is critical to ensure that patients have access to the latest and most effective technology.

The Committee also believes it is important to provide industry with predictable annual increases in application fees. Since the inception of MDUFMA, user fees for certain application types have increased dramatically from year to year. To address these concerns, H.R. 3423 will limit fee increases in FY 2006 and FY 2007 until MDUFMA sunsets on October 1, 2007. This legislation is designed to provide a transition until Congress reauthorizes the program in 2007. During deliberations on the reauthorization of the program the Committee on Energy and Commerce recognizes the need to consider comprehensive changes to the structure of the program to provide for stability and predictability in both application fees and fee revenues for companies that pay user fees and for the FDA.

II. ANALYSIS OF THE LEGISLATION

H.R. 3423 removes the requirement that the total amounts appropriated for FY 2003 through FY 2005 for FDA's device and radiological health program must meet levels specified in MDUFMA before FDA can collect user fees in FY 2006 and FY 2007. As a result, FDA will be able to collect user fees in FY 2006. To avoid similar problems in FY 2007, FDA may continue to collect user fees as long as appropriations are not more than 1 percent below the target amount.

This legislation also provides industry with greater predictability as to the amount by which fees will increase over the next two fiscal years. The fee rate for a premarket approval application (PMA) will increase by 8.5 percent in FY 2006 to $259,600 and by 8.5 percent in FY 2007 to $281,600. Small businesses will receive additional financial relief by expanding the definition of a small business to include entities that reported $100,000,000 or less of gross receipts or sales in their most recent Federal income tax return for a taxable year, except that the small business threshold for an entity to be eligible for a first time, full-fee waiver for a PMA application will remain at $30,000,000. For FY 2006 and FY 2007, FDA will report to Congress on the number of different applications and notifications, and the total amount of fees paid for each type, from businesses with gross receipts or sales at or below $100,000,000.

To provide FDA with a measure of financial security should fee revenues fall short of current projections, the agency may use unobligated carryover balances from fees collected in previous fiscal years if the following conditions are met: (1) Insufficient fee revenues are available in that fiscal year, (2) the agency maintains unobligated carryover balances of not less than one month of operating reserves for the first month of FY 2008, and (3) the agency sends a notice to the Committee on Health, Education, Labor, and Pensions, the Committee on Energy and Commerce, and the Committee on Appropriations of the United States Senate and the United States House of Representatives at least 14 days prior to using these funds. To ensure that funds are not directed away from device safety activities, FDA must certify that the amounts spent by the agency for salaries and expenses to perform device-related activities not pertaining to the review of applications are no less than the amounts spent on those functions in FY 2002 multiplied by the rate of inflation.

Section 301 of MDUFMA added a new subsection (u) to section 502 of the FFDCA that required devices or attachments to a device prominently and conspicuously to bear the name of the manufacturer of the original device or of the reprocessed device, if it was reprocessed, a generally recognized abbreviation of that entity, or a unique and generally recognized symbol identifying the manufacturer. This provision was intended to ensure that the manufacturer of the device, whether the original manufacturer or reprocessor, could be properly identified. In developing the original provisions of Section 301, the Committee believed it was important for device user facilities and the agency to have the ability to correctly identify the responsible party for a device when there is an adverse event associated with a device.

However, under the current language of Section 301, the FDA could waive the branding requirement if compliance is not feasible or compromises the reasonable assurance of safety or effectiveness of the device. For some devices it may be difficult to comply with the marking requirement due to their physical characteristics, such as size and composition. Even if the physical characteristics make it difficult to mark a device, the Committee believes it is important that every device have a mechanism to identify the manufacturer of the product when there is an adverse event.

Reporting of adverse events of medical devices by manufacturers and device user facilities is fundamental to the FDA's post-market